



11/09/2024

Summary view of ARTG# 175422

 **ARTG Name:** Allergan Australia Pty Ltd - Natrelle INSPIRA Truform 1 gel, Textured, Single Lumen Breast implants - Prosthesis, internal, mammary, gel filled (175422 Class III)
Sponsor Name: Allergan Australia Pty Ltd - 17
Therapeutic type: Medical Device
Licence product category: Included
Class: Class III

Active Manufacturers

 **Manufacturer:** Allergan Active (53192)
Country: **United Kingdom**
Step:

No Ceased Manufacturers Located in the Register

Product

 **Product:** Natrelle INSPIRA Truform 1 gel, Textured, Single Lumen Breast implants - Prosthesis, internal, mammary, gel filled (299033)

Product type: **Single Device Product**

Intended purpose: **Intended for breast augmentation or reconstructive mammoplasty.**

Functional description: **Outer shell of Natrelle INSPIRA Truform 1 gel, textured, single lumen breast implants made of silicone elastomer and are pre-filled with cohesive silicone gel designed to simulate natural breast tissue. The Intrashiel shell features a barrier coat between two layers of silicone elastomer to minimise gel diffusion and the Biocell is a textured surface designed to promote tissue adherence.**


Variant information: **Size (cm) 110 - 800 (g), Product name (see guidance docs) Inspira TRL (Low projection), Product name (see guidance docs) Inspira TRM (Moderate projection), Product name (see guidance docs) Inspira TRF (Full projection), Shape Round, Product name (see guidance docs) Inspira TRLP (Low profile Plus projection), Diameter (cm) 9.5 - 17.0, Width (cm) 1.9 - 6.8 cm (projection), Product name (see guidance docs) Inspira TRX (Extra-Full projection)**
GMDN: Prosthesis, internal, mammary, gel filled (36197)

File reference:


No Components Located in the Register

11/09/2024

Summary view of ARTG# 175422

 **ARTG Name:** Allergan Australia Pty Ltd - Natrelle INSPIRA Truform 1 gel, Textured, Single Lumen Breast implants - Prosthesis, internal, mammary, gel filled (175422 Class III)
Sponsor Name: Allergan Australia Pty Ltd - 17
Therapeutic type: Medical Device
Licence product category: Included
Class: Class III

Active Manufacturers

 **Manufacturer:** Allergan Active (53192)
Country: **United Kingdom**
Step:

No Ceased Manufacturers Located in the Register

Product

 **Product:** Natrelle INSPIRA Truform 1 gel, Textured, Single Lumen Breast implants - Prosthesis, internal, mammary, gel filled (528938)

Product type: **Single Device Product**

Intended purpose: **Intended for breast augmentation or reconstructive mammoplasty.**

Functional description: **Outer shell of Natrelle INSPIRA Truform 1 gel, textured, single lumen breast implants made of silicone elastomer and are pre-filled with cohesive silicone gel designed to simulate natural breast tissue. The Intrashiel shell features a barrier coat between two layers of silicone elastomer to minimise gel diffusion and the Biocell is a textured surface designed to promote tissue adherence.**

Variant information: **Product name (see guidance docs) Inspira TRF (Full projection), Product name (see guidance docs) Inspira TRM (Moderate projection), Width (cm) 1.9 - 6.8 cm (projection), Shape Round, Product name (see guidance docs) Inspira TRX (Extra-Full projection), Size (cm) 110 - 800 (g), Product name (see guidance docs) Inspira TRLP (Low profile Plus projection), Diameter (cm) 9.5 - 17.0, Product name (see guidance docs) Inspira TRL (Low projection)**


GMDN: **Prosthesis, internal, mammary, gel filled (36197)**

File reference:


No Components Located in the Register

11/09/2024

Summary view of ARTG# 175425


 **ARTG Name:** Allergan Australia Pty Ltd - Natrelle INSPIRA Truform 2 gel, Textured Single lumen Breast Implants - Prosthesis, internal, mammary, gel filled (175425 Class III)
Sponsor Name: Allergan Australia Pty Ltd - 17
Therapeutic type: Medical Device
Licence product category: Included
Class: Class III

Active Manufacturers

 **Manufacturer:** Allergan Active (53192)
Country: United Kingdom
Step:

No Ceased Manufacturers Located in the Register

Product

 **Product:** Natrelle INSPIRA Truform 2 gel, Textured Single lumen Breast Implants - Prosthesis, internal, mammary, gel filled (299037)

Product type: Single Device Product

Intended purpose: Intended for breast augmentation or reconstructive mammoplasty.

Functional description: Outer shell of Natrelle Soft Touch, Truform 2 gel, textured single lumen breast implants made of silicone elastomer and are pre-filled with cohesive silicone gel designed to simulate natural breast tissue. The Intrashiel shell features a barrier coat between two layers of silicone elastomer to minimise gel diffusion and the Biocell is a textured surface designed to promote tissue adherence.


Variant information: Product name (see guidance docs) Inspira TSLP (Low profile Plus projection), Product name (see guidance docs) Inspira TSX (Extra-Full projection), Product name (see guidance docs) Inspira TSF (Full projection), Size (cm) 110 - 800 (g), Product name (see guidance docs) Inspira TSL (Low projection), Width (cm) 1.9 - 6.8 cm (projection), Diameter (cm) 9.5 - 17.0, Product name (see guidance docs) Inspira TSM (Moderate projection)
GMDN: Prosthesis, internal, mammary, gel filled (36197)

File reference:

No Components Located in the Register

11/09/2024

Summary view of ARTG# 175425

 **ARTG Name:** Allergan Australia Pty Ltd - Natrelle INSPIRA Truform 2 gel, Textured Single lumen Breast Implants - Prosthesis, internal, mammary, gel filled (175425 Class III)


Sponsor Name: **Allergan Australia Pty Ltd - 17**

Therapeutic type: **Medical Device**

Licence product category: **Included**

Class: **Class III**

Active Manufacturers


 **Manufacturer:** Allergan Active (53192)

Country: **United Kingdom**

Step:

No Ceased Manufacturers Located in the Register

Product

 **Product:** Natrelle INSPIRA Truform 2 gel, Textured Single lumen Breast Implants - Prosthesis, internal, mammary, gel filled (528940)

Product type: **Single Device Product**

Intended purpose: **Intended for breast augmentation or reconstructive mammoplasty.**

Functional description: **Outer shell of Natrelle Soft Touch, Truform 2 gel, textured single lumen breast implants made of silicone elastomer and are pre-filled with cohesive silicone gel designed to simulate natural breast tissue. The Intrashiel shell features a barrier coat between two layers of silicone elastomer to minimise gel diffusion and the Biocell is a textured surface designed to promote tissue adherence.**


Variant information: **Product name (see guidance docs) Inspira TSM (Moderate projection), Product name (see guidance docs) Inspira TSL (Low projection), Size (cm) 110 - 800 (g), Diameter (cm) 9.5 - 17.0, Product name (see guidance docs) Inspira TSF (Full projection), Product name (see guidance docs) Inspira TSX (Extra-Full projection), Product name (see guidance docs) Inspira TSLP (Low profile Plus projection), Width (cm) 1.9 - 6.8 cm (projection)**
GMDN: **Prosthesis, internal, mammary, gel filled (36197)**

File reference:


No Components Located in the Register

11/09/2024

Summary view of ARTG# 171512


 **ARTG Name:** Allergan Australia Pty Ltd - Natrelle Truform 3 gel, Textured Single Lumen Breast Implants - Prosthesis, internal, mammary, gel filled (171512 Class III)
Sponsor Name: Allergan Australia Pty Ltd - 17
Therapeutic type: Medical Device
Licence product category: Included
Class: Class III

Active Manufacturers

 **Manufacturer:** Allergan Active (53192)
Country: United Kingdom
Step:

No Ceased Manufacturers Located in the Register

Product

 **Product:** Natrelle Truform 3 gel, Textured Single Lumen Breast Implants - Prosthesis, internal, mammary, gel filled (289926)

Product type: Single Device Product

Intended purpose: Intended for breast augmentation or reconstructive mammoplasty.

Functional description: Outer shell of Natrelle Truform 3 gel, textured single lumen breast implants made of silicone elastomer and are pre-filled with cohesive silicone gel designed to simulate natural breast tissue. The Intrashiel shell features a barrier coat between two layers of silicone elastomer to minimise gel diffusion and the Biocell is a textured surface designed to promote tissue adherence.

Variant information: Product name (see guidance docs) Natrelle 410FX (Full height Extra projection), Size (cm) 100 - 775 (g), Product name (see guidance docs) Natrelle 410LX (Low height Extra projection), Product name (see guidance docs) Natrelle 410LF (Low height Full projection), Product name (see guidance docs) Natrelle 410LM (Low height Moderate projection), Product name (see guidance docs) Natrelle 410LL (Low height Low projection), Product name (see guidance docs) Natrelle 410MF (Moderate height Full projection), Product name (see guidance docs) Natrelle 410FF (Full height Full projection), Product name (see guidance docs) Natrelle 410FL (Full height Low projection), Product name (see guidance docs) Natrelle 410ML (Moderate height Low projection), Product name (see guidance docs) Natrelle 410MM (Moderate height Moderate project), Product name (see guidance docs) Natrelle 410FM (Full height Moderate projection), Width (cm) 2.8 - 7.1 cm (projection), Width (cm) 9.5 - 15.5, Length (cm) 7.6 - 16.0 cm (height), Product name (see guidance docs) Natrelle 410MX (Moderate height Extra projection)

GMDN: Prosthesis, internal, mammary, gel filled (36197)

File reference:

No Components Located in the Register

11/09/2024

Summary view of ARTG# 171475

ARTG Name: Allergan Australia Pty Ltd - Natrelle Soft Touch, Truform 2 gel, Textured, Single Lumen Breast Implants - Prosthesis, internal, mammary, gel filled (171475 Class III)
Sponsor Name: Allergan Australia Pty Ltd - 17
Therapeutic type: Medical Device
Licence product category: Included
Class: Class III

Active Manufacturers

Manufacturer: Allergan Active (53192)
Country: United Kingdom
Step:

No Ceased Manufacturers Located in the Register

Product

Product: Natrelle Soft Touch, Truform 2 gel, Textured, Single Lumen Breast Implants - Prosthesis, internal, mammary, gel filled (289848)

Product type: Single Device Product

Intended purpose: Intended for breast augmentation or reconstructive mammoplasty.

Functional description: Outer shell of Natrelle Soft Touch, Truform 2 gel, textured single lumen breast implants made of silicone elastomer and are pre-filled with cohesive silicone gel designed to simulate natural breast tissue. The Intrashiel shell features a barrier coat between two layers of silicone elastomer to minimise gel diffusion and the Biocell is a textured surface designed to promote tissue adherence.

Variant information: Width (cm) 9.5 - 15.5, Product name (see guidance docs) Natrelle 110 Soft Touch Moderate projection, Shape Anatomical, Diameter (cm) 7.6 - 16.9, Shape Round, Width (cm) 2.6 - 7.1 cm (projection), Size (cm) 80 - 800 (g), Product name (see guidance docs) 410FX Soft touch (Full height Extra projection), Product name (see guidance docs) 410MX Soft touch (Moderate height Extra projection, Product name (see guidance docs) 410LX Soft touch (Low height Extra projection), Product name (see guidance docs) 410LF Soft touch (Low height Full projection), Product name (see guidance docs) 410LM Soft Touch (Low height Moderate projection), Product name (see guidance docs) 410LL Soft touch (Low height Low projection), Product name (see guidance docs) 410MF Soft touch (Moderate height Full projection), Product name (see guidance docs) 410FF Soft touch (Full height Full projection), Product name (see guidance docs) 410FL Soft touch (Full height Low projection), Product name (see guidance docs) 410ML Soft touch (Moderate height Low projection), Product name (see guidance docs) 410MM Soft Touch (Moderate height Moderate project), Product name (see guidance docs) 410FM Soft Touch (Full height Moderate projection), Product name (see guidance docs) Natrelle 120 Soft Touch Full projection, Length (cm) 7.6 - 16.0 cm (height)


GMDN: Prosthesis, internal, mammary, gel filled (36197)

File reference:


No Components Located in the Register

11/09/2024

Summary view of ARTG# 171387

 **ARTG Name:** Allergan Australia Pty Ltd - Natrelle Truform Dual gel, Textured Single Lumen Breast Implants - Prosthesis, internal, mammary, gel filled (171387 Class III)
Sponsor Name: Allergan Australia Pty Ltd - 17
Therapeutic type: Medical Device
Licence product category: Included
Class: Class III

Active Manufacturers

 **Manufacturer:** Allergan Active (53192)
Country: **United Kingdom**
Step:

No Ceased Manufacturers Located in the Register

Product

 **Product:** Natrelle Truform Dual gel, Textured Single Lumen Breast Implants - Prosthesis, internal, mammary, gel filled (289588)

Product type: **Single Device Product**

Intended purpose: **Intended for breast augmentation or reconstructive mammoplasty.**

Functional description: **Outer shell of Natrelle Soft Touch, Truform 2 gel, textured single lumen breast implants made of silicone elastomer and are pre-filled with cohesive silicone gel designed to simulate natural breast tissue. The Intrashiel shell features a barrier coat between two layers of silicone elastomer to minimise gel diffusion and the Biocell is a textured surface designed to promote tissue adherence.**

Variant information: **Size (cm) 130 - 630 (g), Product name (see guidance docs) Natrelle 510FX (Full height Extra projection), Product name (see guidance docs) Natrelle 510MX (Moderate height Extra projection), Product name (see guidance docs) Natrelle 510LX (Low height Extra projection), Width (cm) 4.4 - 7.0 cm (projection), Width (cm) 9.5 - 15.5, Length (cm) 7.6 - 16.0 cm (height)**


GMDN: **Prosthesis, internal, mammary, gel filled (36197)**

File reference:

No Components Located in the Register

11/09/2024

Summary view of ARTG# 169956

 **ARTG Name:** Allergan Australia Pty Ltd - Natrelle Double Lumen Gel/Saline Breast Implants - Prosthesis, mammary, internal, gel/saline-filled, inflatable (169956 Class III)

Sponsor Name: **Allergan Australia Pty Ltd - 17**

Therapeutic type: **Medical Device**

Licence product category: **Included**

Class: **Class III**

Active Manufacturers

 **Manufacturer:** Allergan Active (53192)

Country: **United Kingdom**

Step:

No Ceased Manufacturers Located in the Register

Product

 **Product:** Natrelle Double Lumen Gel/Saline Breast Implants - Prosthesis, mammary, internal, gel/saline-filled, inflatable (285712)

Product type: **Single Device Product**

Intended purpose: **Intended for breast augmentation or reconstruction mammoplasty.**

Functional description: **Outer shell is filled with silicone gel, and an inflatable inner shell filled with saline. The Natrelle 150 gel/saline implants have textured surface engineered with a deep open pore design for firm tissue adherence and a barrier coat between two layers of silicone elastomer to minimise gel diffusion. It also includes a magnetic resonance imaging compatible self-sealing mini remote injection site which contains a titanium needle guard.**

Variant information: **Length (cm) 8.0 - 17.0 cm (height), Volume (mL) 45 - 360 gel filled, Width (cm) 9.5 - 16.0, Volume (mL) 90-440 saline filled, Size (cm) 135 - 760 cm cube**

GMDN: **Prosthesis, mammary, internal, gel/saline-filled, inflatable (45417)**

File reference:

No Components Located in the Register

11/09/2024

Summary view of ARTG# 175797

 **ARTG Name:** Allergan Australia Pty Ltd - Natrelle Tissue Expanders - Skin expander (175797 Class III)


Sponsor Name: **Allergan Australia Pty Ltd - 17**

Therapeutic type: **Medical Device**

Licence product category: **Included**

Class: **Class III**

Active Manufacturers

 **Manufacturer:** Allergan Active (53192)

Country: **United Kingdom**

Step:

No Ceased Manufacturers Located in the Register

Product

 **Product:** Natrelle Tissue Expanders - Skin expander (299757)

Product type: **Single Device Product**

Intended purpose: The device is intended to be implanted temporarily into the breast to enlarge the dimensions of a skin flap for a long term implant at a later date.

Functional description: The Tissue Expander is designed for breast tissue expansion to achieve enough relaxed skin and soft tissue with the expander in order to provide cover for a permanent breast implant, yielding softer, more natural results. These expanders can also be used to create additional skin to close a defect after scar excision. All Tissue Expanders require periodic, incremental inflation with sterile saline for injection until the desired amount of tissue is developed.

Variant information: Product name (see guidance docs) 133 SV (Short height Variable projection), Product name (see guidance docs) 133 LV (Low height Variable projection), Product name (see guidance docs) 133 SX (Short height Extra full projection), Product name (see guidance docs) 133FX (Full height Extra full projection), Product name (see guidance docs) 133 MX (Moderate height Extra full projection), Volume (mL) 150 - 950, Product name (see guidance docs) 133 FV (Full height Variable projection), Shape Anatomical, Length (cm) 4.7 - 8.1 cm (Projection), Length (cm) 7.6 - 16.5 cm (Height), Width (cm) 11.0 - 16.0 cm, Product name (see guidance docs) 133 MV (Moderate height Variable projection)


GMDN: Skin expander (45187)

File reference:


No Components Located in the Register

11/09/2024

Summary view of ARTG# 175420


 **ARTG Name:** Allergan Australia Pty Ltd - Natrelle Truform1 gel, Textured, Single Lumen Breast Implants - Prosthesis, internal, mammary, gel filled (175420 Class III)
Sponsor Name: Allergan Australia Pty Ltd - 17
Therapeutic type: Medical Device
Licence product category: Included
Class: Class III

Active Manufacturers

 **Manufacturer:** Allergan Active (53192)
Country: *United Kingdom*
Step:

No Ceased Manufacturers Located in the Register

Product

 **Product:** Natrelle Truform1 gel, Textured, Single Lumen Breast Implants - Prosthesis, internal, mammary, gel filled (299031)

Product type: *Single Device Product*

Intended purpose: *Intended for breast augmentation or reconstructive mammoplasty.*

Functional description: *Outer shell of Natrelle Truform 1 gel, textured, single lumen breast implants made of silicone elastomer and are pre-filled with cohesive silicone gel designed to simulate natural breast tissue. The Intrashiel shell features a barrier coat between two layers of silicone elastomer to minimise gel diffusion and the Biocell is a textured surface designed to promote tissue adherence.*

Variant information: *Product name (see guidance docs) Natrelle 120 (High profile), Product name (see guidance docs) Natrelle 110 (Moderate profile), Size (cm) 90 - 650 (g), Width (cm) 2.0 - 5.0 cm (projection), Shape Round, Diameter (cm) 8.7 - 15.5*


GMDN: *Prosthesis, internal, mammary, gel filled (36197)*

File reference:

No Components Located in the Register

11/09/2024

Summary view of ARTG# 171388

 **ARTG Name:** Allergan Australia Pty Ltd - Natrelle Saline-filled, Textured Breast Implants - Prosthesis, internal, mammary, inflatable (171388 Class III)

Sponsor Name: **Allergan Australia Pty Ltd - 17**

Therapeutic type: **Medical Device**

Licence product category: **Included**

Class: **Class III**

Active Manufacturers

 **Manufacturer:** Allergan Active (53192)

Country: **United Kingdom**

Step:

No Ceased Manufacturers Located in the Register

Product

 **Product:** Natrelle Saline-filled, Textured Breast Implants - Prosthesis, internal, mammary, inflatable (289589)

Product type: **Single Device Product**

Intended purpose: **Intended for breast augmentation or reconstructive mammoplasty.**

Functional description: **Natrelle saline filled inflatable breast implants have textured surface with a deep open pore design to promote tissue adherence. The saline is filled at the time of surgery.**

The saline filled implants are round or anatomical in shape with diaphragm valve designed for filling and air removal.

Variant information: **Volume (mL) 120 - 685, Diameter (cm) 9.0 - 14.4, Product name (see guidance docs) Natrelle 468, Product name (see guidance docs) Natrelle 363, Product name (see guidance docs) Natrelle 168, Width (cm) 3.0 - 6.1 cm projection, Shape Round, Length (cm) 9.5 - 15.0 cm (height), Width (cm) 10.0 - 15.8, Shape Anatomical**

GMDN: **Prosthesis, internal, mammary, inflatable (36196)**

File reference:

No Components Located in the Register