



# Five questions to ask your health professional before you get a medical implant

Medical devices that are implanted inside or on the surface of your body are considered higher risk therapeutic goods, and the decision to get one should not be taken lightly. A medical implant will often be in your body for a significant amount of time, so it's important that you discuss the risks and benefits of all options available to you with your health professional before making a decision. The following questions will help guide your conversation

## 1. Do I really need this medical implant?

Alternative treatments including medicines and lifestyle changes may be available to treat your condition. You should discuss with your health professional:

- What will happen if I don't have the device implanted?
- Are there alternative options to the surgical procedure or this particular type of device?
- What are the risks and benefits of the alternative options?

## 2. What are the risks/benefits?

There are risks with any medical procedure. Some are temporary or expected, others can be more serious or have lifelong impacts. You should discuss with your health professional:

- What are the potential side effects from the recommended procedure or implant (also called 'adverse events')?
- What side effects may be permanent?
- Can I do anything to prevent side effects before or after the procedure?
- What types of people are more likely to experience side effects?
- What should I do if I experience side effects?

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- Could having the implant eventually lead to another surgical procedure?
- Is the implant permanent and, if not, how hard it is to remove or replace?
- What is the cost of the implant and how long it will last?

### 3. Is the medical implant approved?

The Therapeutic Goods Administration (TGA) approves implants for particular purposes where clinical data demonstrates that their use can be beneficial. You should discuss with your health professional:

- Is the recommended implant approved by the TGA for the proposed use?
- Is this a new product or procedure?
- How many times has the health professional performed this procedure or used this implant for the proposed use?
- What is the success rate of the procedure and implant for people like me?

### 4. Where can I get more information

More information about your implant and procedure may be available. Discuss with your health professional:

- Where can I find the implant’s patient information leaflet?
- Is there more information about the implant or procedure available? Where can I find this information?
- Where can I find up-to-date information about the implant after the procedure?
- Is there a patient implant card for this device? This card contains information about the device and will help you locate information about it in the future – if there is one, remember to ask for it.

### 5. What happens if I experience an adverse event?

The TGA monitors the ongoing safety and quality of medical devices by assessing adverse event reports from patients and health professionals. You should report any adverse events you experience to the TGA as well as your health professional. In an emergency, your first point of call should always be 000.

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#### Further information

Further information on how to report an adverse event can be found at:

<https://www.tga.gov.au/reporting-problems>