TMJ Fossa Eminence Prosthesis™- P000035

This is a brief overview of information related to FDA's approval to market this product. See the links below to the Summary of Safety and Effectiveness and product labeling for more complete information on this product, its indications for use, and the basis for FDA's approval.

Product Name:	TMJ Fossa Eminence Prosthesis™
Manufacturer:	TMJ Implants Incorporated
Address:	17301 West Colfax Avenue, Suite 135, Golden, Colorado 80401
Approval Date:	February 27, 2001
Approval Letter:	http://www.fda.gov/cdrh/pdf/p000035a.pdf

What is it? The Fossa Eminence device is a metal implant that lines the skull portion (called the glenoid fossa) of the joint that attaches the jaw to the skull (called the temporomandibular joint, or "TMJ").

See Illustration

How does it work? This device provides a smooth surface for the movement of the jaw as it is opened and closed.

When is it used? This implant is used when moderate to severe pain in the TMJ has not responded to noninvasive therapies such as medication, special appliances worn in the mouth, or physical therapy.

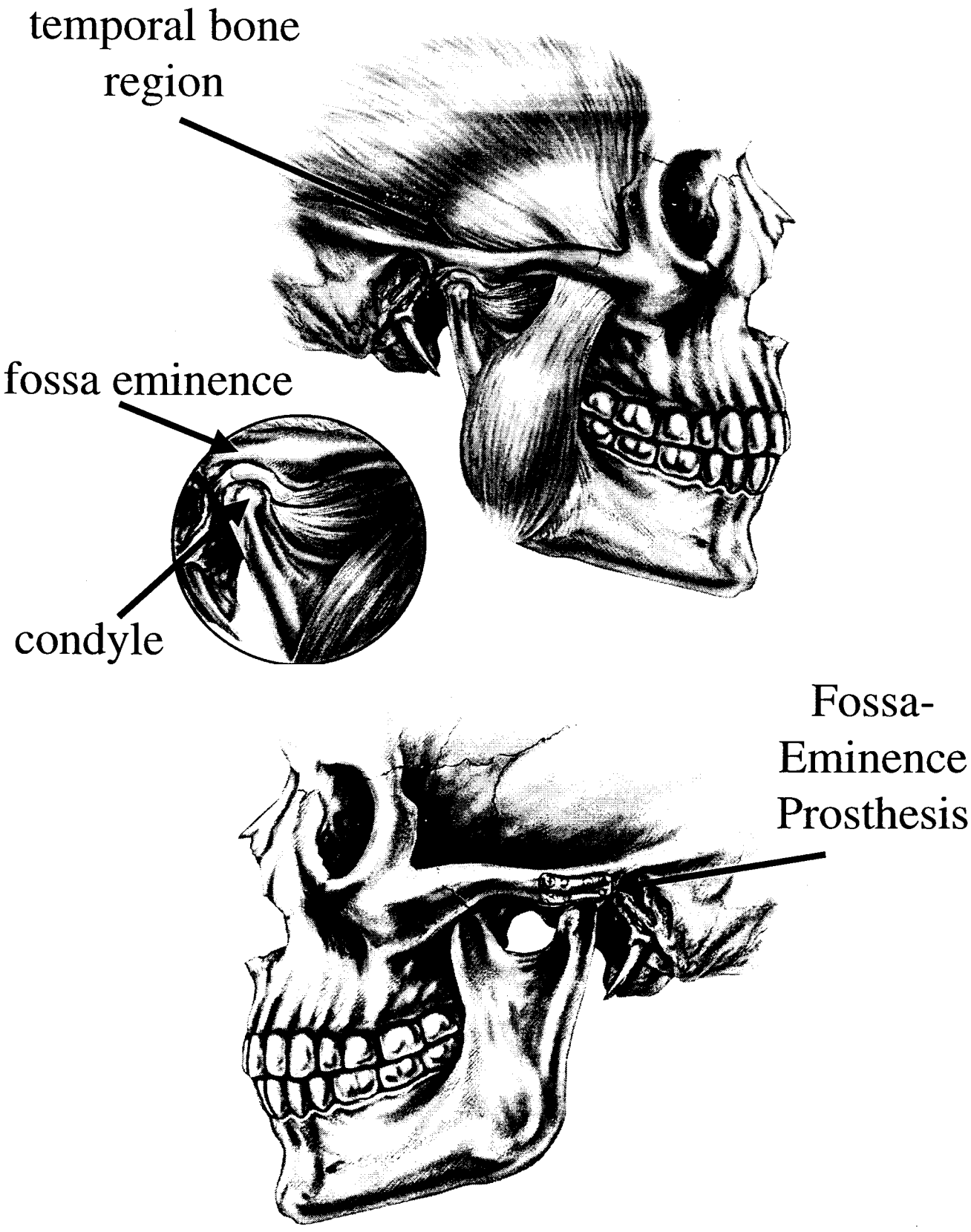
What will it accomplish? The Fossa Eminence is intended to reduce pain and increase the range of motion of the jaw.

When should it not be used? The implant should not be used if there is:

- An infection in the jaw joints
- If there is not enough bone to support the TMJ implant
- If the patient is allergic to the implant material
- If the patient severely grinds his or her teeth and might fracture the implant
- If there is cancer in the head or neck area
- If the patient will be unable to do the long term follow-up therapy

Additional information: Summary of Safety and Effectiveness is available at:
http://www.fda.gov/cdrh/pdf/p000035.html

(Updated 4/02/01)


temporal bone region
fossa eminence
condyle
Fossa-Eminence Prosthesis