



**Regulatory,
quality and
clinical
affairs**

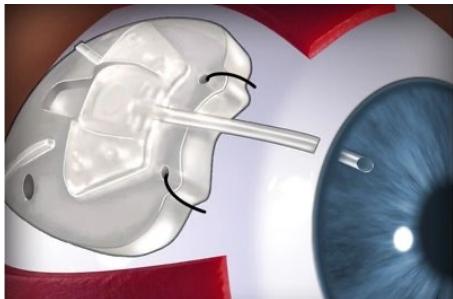
NX-451 – What to know
when working with
medical devices

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Classification exercise

Aqueous shunts



Intended Use:

Aqueous shunts are designed to reduce IOP in individuals with neovascular glaucoma or in cases where medical and conventional surgical treatments have failed.

Mode of Action:

These devices function by creating an alternative pathway for the drainage of aqueous humor—the fluid produced within the eye.

By facilitating the outflow of this fluid, aqueous shunts help lower Intra Ocular Pressure (IOP), thereby reducing the risk of optic nerve damage and preserving vision.

The procedure involves placing the shunt into the eye to improve fluid drainage and pressure regulation.

Classification exercise

Adhesive bandage



Intended Use:

Cover and protect minor wounds to shield the wound from external contaminants, such as dirt and bacteria, reducing the risk of infection.

Mode of Action:

The bandage acts as a physical barrier against mechanical irritation, friction, and potential contaminants, thereby reducing the risk of infection. The central absorbent pad draws exudate away from the wound, preventing maceration and promoting a moist healing environment.

Classification exercise

Intravenous (IV) Catheter



Intended Use:

An Intravenous (IV) catheter is used to administer fluids, medications, or nutrients directly into a patient's vein. It is commonly used for hydration, delivering antibiotics, pain management, blood transfusions, and intravenous nutrition. IV catheters are also used for drawing blood and providing access for long-term treatments such as chemotherapy.

Mode of Action:

An Intravenous (IV) catheter works by being inserted into a vein, typically in the arm or hand. Once in place, it creates a direct pathway for fluids, medications, or nutrients to be delivered into the bloodstream. Peripheral IV catheters (those inserted into veins in the arms or hands) are used for 1 to 4 days.

Classification exercise

Peripheral drug-eluting stent



Intended Use:

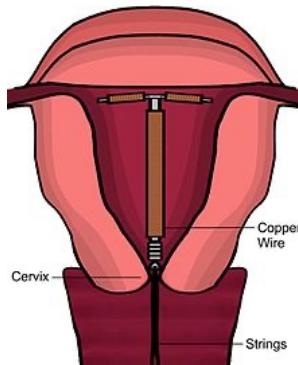
A peripheral drug-eluting stent is primarily used to treat peripheral artery disease (PAD), a condition where arteries in the limbs, typically the legs, become narrowed or blocked. This stent is implanted to restore blood flow in peripheral arteries and prevent restenosis (re-narrowing of the artery) after an angioplasty or other procedures designed to open up blocked arteries.

Mode of Action:

The peripheral drug-eluting stent works by mechanically supporting the artery to keep it open after the blockage has been cleared. The stent is coated with a drug, typically paclitaxel, which is slowly released into the surrounding tissue over time. This drug helps prevent excessive cell growth (such as smooth muscle cells) at the site of the stent, thereby reducing the risk of restenosis.

Classification exercise

IUD



Intended Use:

A non-hormonal intrauterine contraceptive device (IUD) is primarily used for contraception. It is inserted into the uterus to prevent pregnancy. The device is suitable for long-term contraception, often providing effective birth control for several years without requiring daily attention.

Mode of Action:

A non-hormonal IUD, such as the copper IUD, works by releasing copper ions into the uterus, which are toxic to sperm. This creates an environment that is inhospitable to sperm, preventing them from fertilizing an egg. Additionally, the presence of the IUD triggers a local inflammatory response within the uterus, which further impedes sperm movement and egg implantation. The copper IUD does not interfere with the body's hormone levels, distinguishing it from hormonal IUDs.

Classification exercise – proposed classification

Aqueous shunts

Non active, invasive device, long term

Class IIb according to rule 8

Adhesive bandage

Non active, non invasive, in contact with injured skin, act as mechanical barrier

Class I according to rule 4

Intravenous (IV) Catheter

Non active, Short term, surgically invasive, intended to administer medicines

Class IIb according to rule VII

Peripheral drug-eluting stent

Devices incorporating integral medicinal substance for ancillary action

Class III according to rule 14

Surgically invasive - Long term use – Contact with central circulatory

Class III according to rule 8

Non-hormonal IUD

Devices used for contraception, long term invasive devices,

Class III according to rule 15

