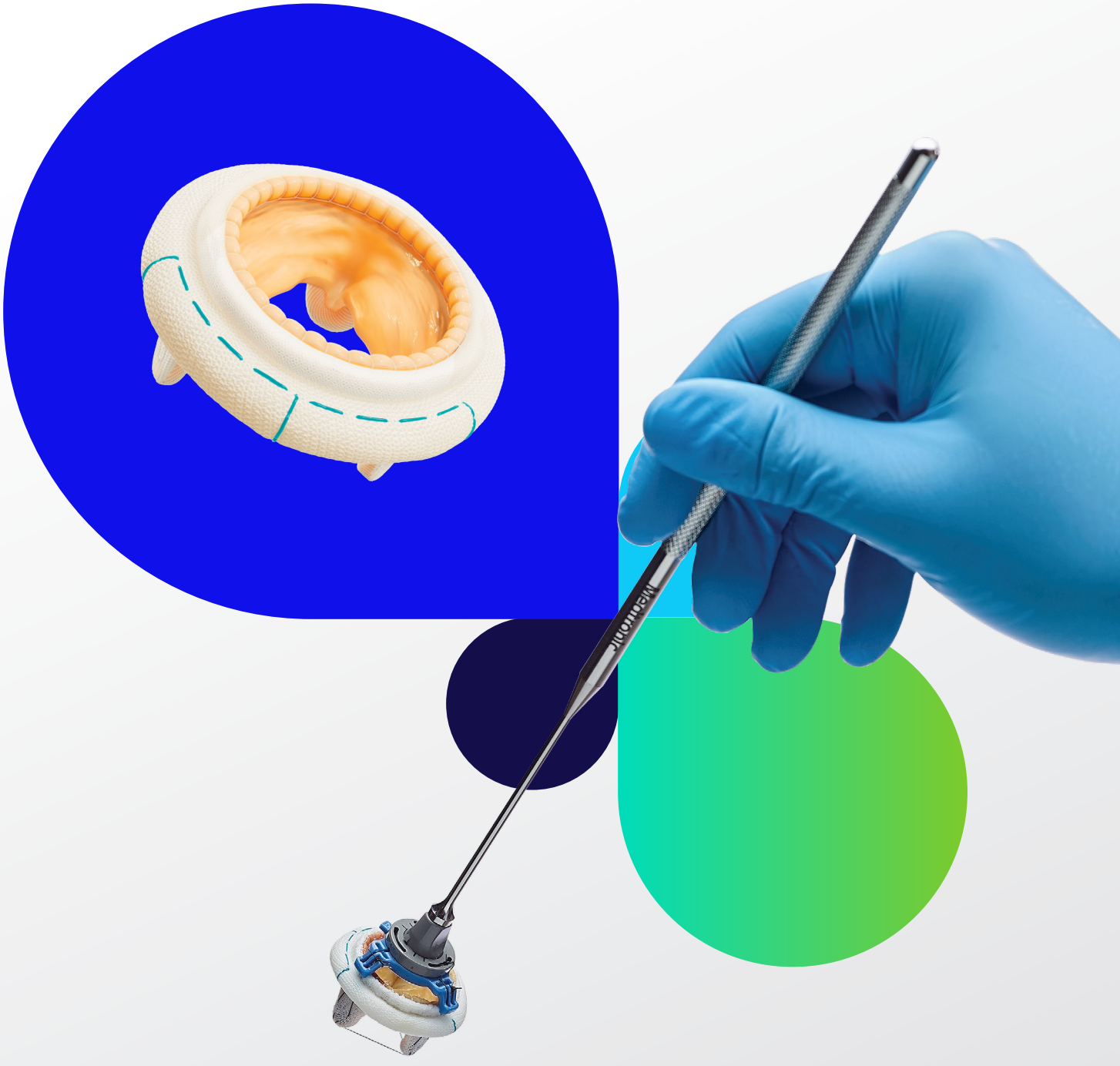
Medtronic

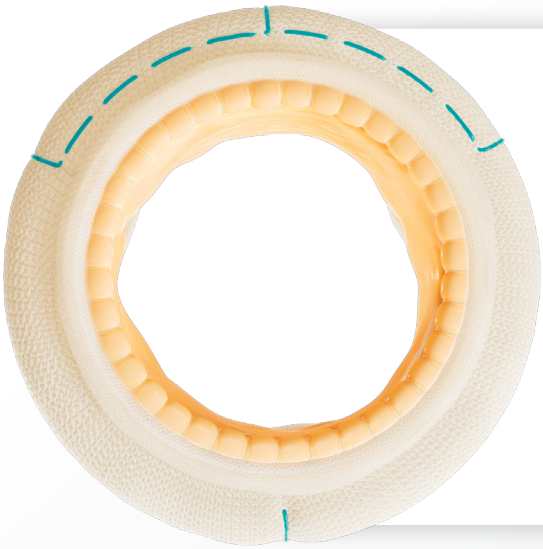
## Mosaic Neo™ mitral bioprosthesis

# Intuitive by design. Proven to perform.



# Created for LVOT clearance

With its atrialised design, wide anterior interstrut distance and clear orientation cuff markers, the Mosaic Neo valve offers a unique set of features to help enable clearance of the left ventricular outflow tract (LVOT).



## The native-porcine difference

The native-porcine design of the Mosaic Neo valve offers one wider leaflet spaced at 135° – this wider interstrut distance at the anterior annulus is designed to enable LVOT clearance and accommodate ventricular flow.†,[1-3]

## Atrialised design

The atrialised design of the Mosaic Neo valve reduces left ventricular (LV) protrusion by up to 23% compared to the Mosaic™ mitral valve.†,[4,5]

## Radiopaque inflow marker

Provides an easy-to-identify landing zone for transcatheter mitral valve-in-valve procedures.[6]

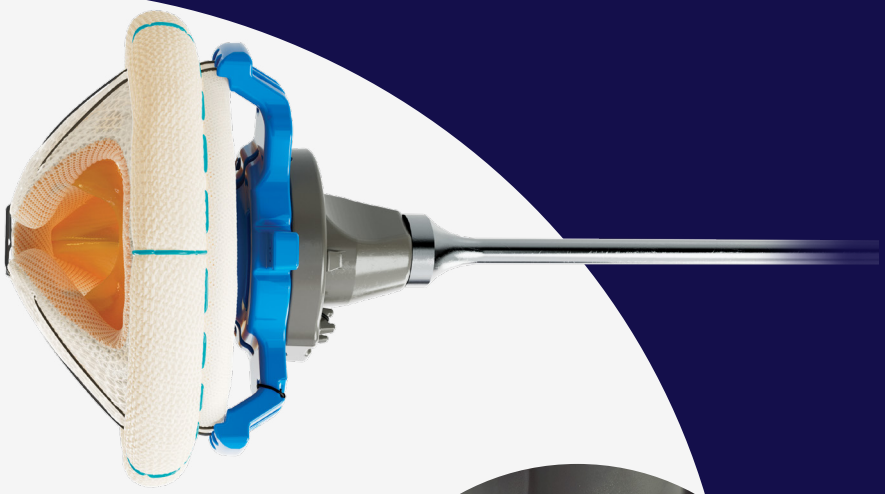
† Bench test, may not be indicative of clinical performance.

# Enhanced for ease

The Mosaic Neo platform offers multiple enhancements designed to enable a straightforward mitral valve replacement procedure. Updated smooth-barrel sizers, the Cinch™ mechanism, and a quick-detach handle release work together to simplify workflow – delivering a smooth implant experience from start to finish.

## Cinch™ implant system

- Facilitates valve implantation particularly through tight patient anatomy and small incisions.[7]
- Helps prevent suture looping.[7]
- Designed to protect the tissue from inadvertent damage.[8]



## Quick-detach handle removal

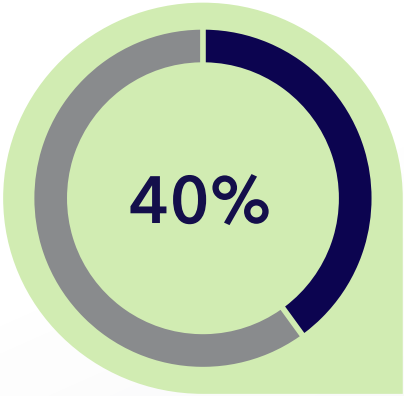
- Eliminates the need to unscrew the handle.[8,9]
- A single-cut handle release for quick detachment and a simplified implantation process.[8,9]

## Simplified sizers

- Pre-attached smooth barrel sizers offer a simple mitral annular measurement.[6,9]

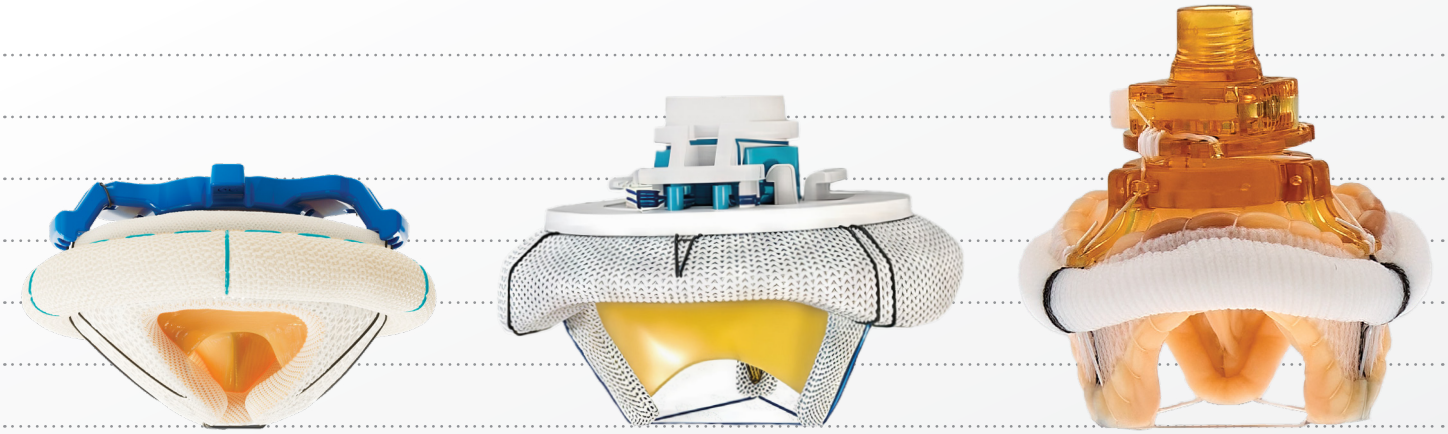
# Streamlined for minimally invasive

With the small incision sizers and the low implant profile, the Mosaic Neo valve sets a new benchmark for ease of use in small incision surgery,[9] offering an implant profile which is reduced up to 40% versus other commercially available tissue mitral valves.[‡,10-12]




**Reduced implant profile**

# Best-in-class implant profile[‡,10-12]



**Mosaic Neo™ mitral valve**
**Size 29**
**Implant profile height: 21.00 mm**

**MITRIS RESILIA™* mitral valve**
**Size 27**
**Implant profile height: 26.40 mm**

**Epic™* Plus mitral valve**
**Size 29**
**Implant profile height: 34.90 mm**

‡ Dimensional measurements taken with Mosaic Neo valve size 29, Epic™* Plus size 29, MITRIS RESILIA™* size 27 based on OD comparability.

# Proven to perform

A next-generation valve offering industry-leading, unsurpassed durability and excellent hemodynamics as demonstrated by the Mosaic mitral valve.[13,15-18] The Mosaic Neo valve carries forward a legacy of performance surgeons have trusted for decades – now enhanced for the future.

## Over half a million patients served with the AOA™ tissue treatment


The Mosaic Neo valve benefits from AOA treatment, which reduces calcification in the tissue leaflets and is designed to enhance long-term valve durability as supported by more than 30 years of its clinical use encompassing over half a million patients.[§,14,19-21]

§ The benefits of AOA tissue treatment have been demonstrated through animal testing. No direct clinical evaluation of the benefits of AOA treatment in humans has been conducted.

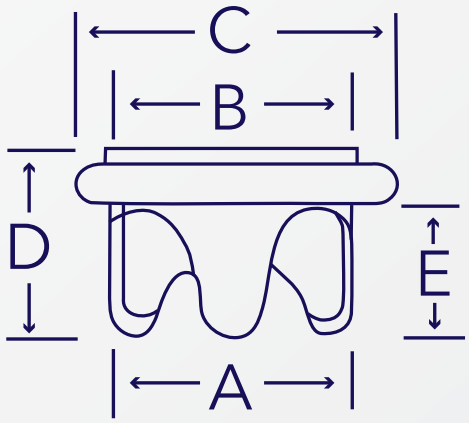
Key risks associated with the use of bioprosthetic heart valves include: structural deterioration, nonstructural dysfunction, and endocarditis.

# Ordering information

| Order number | A Valve size (mm) (stent O.D.Ω) | B Orifice diameter (mm) (stent I.D.) | C Suture ring diameter (mm) | D Valve height (mm) | E Ventricular protrusion (mm) |
|---|---|---|---|---|---|
| 310MN25 | 25 | 22.5 | 33.5 | 18.0 | 11.0 |
| 310MN27 | 27 | 24.0 | 35.5 | 19.0 | 11.5 |
| 310MN29 | 29 | 26.0 | 38.0 | 20.5 | 12.5 |
| 310MN31 | 31 | 28.0 | 41.0 | 22.0 | 14.0 |
| 310MN33 | 33 | 30.0 | 43.5 | 23.0 | 14.5 |

## Accessories

| Item number | Description |
|---|---|
| 7639 | Handle (234 mm length), to be used with Mosaic and Mosaic Neo bioprostheses |
| 7639XL | XL Handle (368 mm length), to be used with Mosaic and Mosaic Neo bioprostheses |
| S310MNH | Mosaic Neo mitral sizers |
| T310MNH | Tray for Mosaic Neo mitral sizers |
| S310MNS | Mosaic Neo mitral small incision sizers |
| T310MNS | Tray for Mosaic Neo mitral small incision sizers |




**A =** Valve size (stent O.D.Ω)
**B =** Orifice diameter (stent I.D.)
**C =** Suture ring diameter
**D =** Valve height
**E =** Ventricular protrusion

**Nominal values in millimeters**

Ω Stent O.D. equivalent to annulus diameter.

## References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## Important Safety Information

**Mosaic Neo mitral bioprothesis**

**Indications:** The Mosaic Neo mitral bioprosthesis is indicated for the replacement of a malfunctioning native or prosthetic mitral heart valve.

**Contraindications:** No contraindications for use of this device are known.

**Warnings/Precautions/Adverse Events:** As with any implanted medical device, there is potential for patient immunological response, including an allergic response. Care should be exercised in patients with hypersensitivities to the device materials, such as nickel. Calcific degeneration could cause accelerated deterioration of the valve in patients with altered calcium metabolism (for example, chronic renal failure, hyperparathyroidism). Calcification may occur earlier in children, adolescents, or young adults. Premature calcification may also occur in older adults who accept a biologic prosthesis. Patients with a bioprosthesis that require chronic anticoagulation are at additional risk of bleeding. Stenosis and regurgitation of the bioprosthesis may occur in patients with coagulation disorders such as AT3 deficiency. Paravalvular leak is more likely to occur in patients with aneurysmal aortic or degenerative conditions, cystic medial necrosis, or Marfan syndrome. Adverse events can include: allergic reaction/immunologic response, aneurysm or pseudoaneurysm, aortic tissue damage, cardiac arrest, cardiac arrhythmias, cardiac tamponade, embolism or thromboembolism, endocarditis, heart block, heart failure, hemodynamic instability, hemolysis, hemolytic anemia, anticoagulant/antiplatelet-related hemorrhage, hypertension or hypotension, inflammatory reaction, infection other than endocarditis, transvalvular or paravalvular leak, mitral tissue damage, myocardial infarction, nonstructural dysfunction (leaflet entrapment/impingement, obstructive pannus ingrowth, suture dehiscence, inappropriate sizing), pericardial effusion, pleural effusion, prosthesis regurgitation, prosthesis stenosis, stroke, structural deterioration (calcification, leaflet tear), thrombus or thrombosis. These complications could lead to reoperation, explant of the bioprosthesis, permanent disability or organ damage, or death.

For a listing of indications, contraindications, precautions, warnings, and potential adverse events, please refer to the Instructions for Use (IFU). If applicable, consult electronic IFUs (eIFUs) at medtronic.com/manuals. Note: eIFUs can be viewed using a current version of any major internet browser.

**Mosaic mitral bioprosthesis**

**Indications:** For the replacement of malfunctioning native or prosthetic mitral heart valves.

**Contraindications:** None known.

**Warnings/Precautions/Adverse Events:** Accelerated deterioration due to calcific degeneration of bioprosthesis may occur in children, adolescents, young adults, and patients with altered calcium metabolism (e.g., chronic renal failure, hyperparathyroidism). Adverse events can include angina, cardiac arrhythmia, cardiac dysrhythmias, death, endocarditis, infection other than endocarditis, heart failure, hemolysis, hemolytic anemia, hemorrhage, transvalvular or paravalvular leak, myocardial infarction, nonstructural dysfunction, stroke, structural deterioration, thromboembolism, or valve thrombosis.

For a list of indications, contraindications, precautions, warnings, and potential adverse events, please refer to the instructions for use. For countries that use (electronic instructions for use) eIFUs, consult instructions for use at this website medtronic.com/manuals.

This material should not be considered the exclusive source of information, it does not replace or supersede information contained in the device manual(s). Please note that the intended use of a product may vary depending on geographical approvals. See the device manual(s) for detailed information regarding the intended use, the (implant) procedure, indications, contraindications, warnings, precautions, and potential adverse events. For an MRI compatible device(s), consult the MRI information in the device manual(s) before performing an MRI. If a device is eligible for eIFU usage, instructions for use can be found at Medtronic's website manuals.medtronic.com. Manuals can be viewed using a current version of any major internet browser. For best results, use Adobe Acrobat® Reader with the browser. Medtronic products placed on European markets bear the CE mark and the UKCA mark (if applicable). For any further information, contact your local Medtronic representative and/or consult Medtronic's websites.

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