

Zimmer Biomet's Personal Protection System

The *TotalShield® and TotalShield® II* Surgical Togas and Hoods are for use with the TotalShield and TotalShield II Surgical Helmet Systems, respectively, and are intended to be worn by surgical personnel to provide a barrier between the operating environment and the surgical personnel in order to protect against contamination and/or exposure of infectious body fluids and harmful microorganisms.

The TotalShield and TotalShield II System product lines (helmet, hood, toga) are Class II medical devices in the US and require a 510k (premarket notification). These products are considered PPE (Personal Protective Equipment) and were designed to protect users from in-motion debris (bone chips, blood splatters, etc.) and blood strike-through during surgical procedures. Unfortunately, this product was not designed for protection against airborne viruses such as the Coronavirus. **In fact, these products, per the Instruction for Use provided with the device, are not to be utilized as respiratory protection systems.** During use, the fan will draw air into the hood/toga area to ventilate and remove CO₂. The intake of this air does not have adequate filtration for the purpose of removing viruses. Additionally, if the hood/toga were to be used without the helmet/fan, the user could be exposed to CO₂ buildup beyond what is identified by the associated standard, potentially causing harm to the user.

TotalShield Surgical Helmet Cleaning Recommendation

Zimmer Biomet recommends cleaning the TotalShield and TotalShield II Surgical Helmet System using a mild detergent solution with a neutral PH or isopropyl alcohol. To achieve low level disinfection: Wipe the exterior of the device with damp cloth using 70% isopropanol to remove visible soil, and keep the surface wet with 70% isopropanol for a minimum of 1 minute.

AAMI Level Testing

The Association for the Advancement of Medical Instrumentation (AAMI) has established a classification system for protective apparel based on efficiency against liquid or liquid borne microorganism penetration. Zimmer Biomet offers multiple hoods and togas made from material in critical and noncritical zones that pass AAMI Level testing, keeping you protected against infectious body fluids and harmful microorganisms. Critical zones comprise of the front of the toga from the chest to the knees and the sleeves above the elbow to the cuff of the sleeve.

Protection levels by part numbers for Zimmer Biomet’s disposable offerings of Hoods and Togas. These come sterile and are single use items only.

TotalShield II Togas	Zippered Surgical Toga 00-9920-411-10, Large 00-9920-412-10, X-Large 00-9920-413-10, 2X-Large 00-9920-414-10, 3X-Large	Sleeve Material, Toga Reinforced Chest- AAMI Level 4 Gown Material- AAMI Level 2 Sleeve Seams- AAMI Level 1 Filter Material- N/A
TotalShield II Hood	Surgical Hood 00-9920-401-12	Hood Material- AAMI Level 2* Filter Material- N/A
TotalShield I Togas	Zippered Toga 00-9900-310-10, Regular 00-9900-311-10, Large 00-9900-312-10, X-Large	Sleeve Material, Sleeve Seam, Toga Material- AAMI Level 3 Filter Material- 99% VFE min, 97% BFE min
TotalShield I Hood	Surgical Hood 00-9900-301-12	Hood Material- AAMI Level 3* Filter Material- 99% VFE min, 97% BFE min

*Per AAMI PB70, Hood Material is exempt from the standard, but the material meets the requirements at the level noted.

If you have any questions with our product offering for PPE, please contact:

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Intended for Healthcare Professionals. For indications, contraindications, warnings, precautions, potential adverse effects and patient counseling information, see the package insert and user manual or contact your local representative; visit www.zimmerbiomet.com for additional product information.