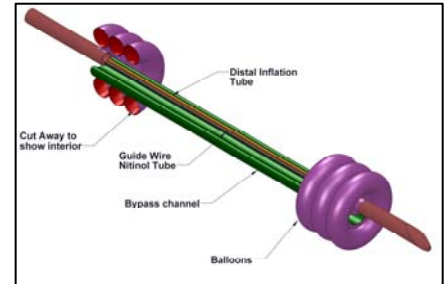


# Zone Isolation and Bypass System (Zone)

The MINT team is developing an innovative medical device called the Zone Isolation and Bypass System (Zone), which enables clinicians to perform true endovascular vessel repair for the first time. Zone also functions as a triage device that can be inserted percutaneously to prepare a patient for transport to a center for advanced treatment.



## The Unmet Clinical Need

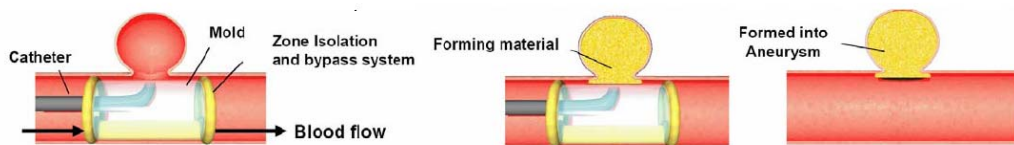
Minimally invasive procedures and enabling medical devices are critically needed to endolumenally treat vascular pathologies and trauma. Clinicians are in need of devices that create a stable, isolated therapeutic region free of blood flow where they can perform surgical procedures (e.g. repair of vascular ruptures, punctures, dissections, and tears). These same devices must also allow blood to continue flowing past the injury site to continue supplying distal tissues with oxygen and nutrients.

In addition to these needs in vascular repair, there exists a significant need for a device to stabilize patients with vascular trauma, isolate the region of bleeding or rupture, and maintain distal perfusion in order to permit the safe transport of patients to an appropriate location for advanced therapy. These unmet clinical needs exist in both civilian and military environments.

## MINT's Solution

The Zone device uses a system of concentric balloons to isolate a segment of vessel, establish a region free from flowing blood and resultant shear forces, and control pressure on the vessel wall. These features allow vascular surgeons to perform precise surgical operations while blood continues flowing downstream through Zone's bypass channel.

Clinicians can deliver Zone through a standard guide catheter and advance the device endovascularly to the injury site using standard guide wire techniques. Once the device is in position, clinicians can inflate the forward and aft balloons to isolate the vessel segment for treatment. The isolated zone can be cleared of blood and the intraluminal pressure adjusted to requisite levels. An anchored surgical platform is thus created into which imaging devices and surgical tools can be passed and surgical glues or similar materials can be applied.



Zone also has valuable applications in aneurysm repair, whereby interventionalists can deploy Zone at the site of an aneurysm, halt blood flow, depressurize the Zone and adjacent aneurysm to reduce the risk of aneurysm rupture, and treat the aneurysm using endovascular tools. One such endovascular tool is MINT's Injectable Mold product, which enables clinicians to create a biodegradable and bioregenerative mold within the therapeutic space created by Zone, treating the vascular injury while accelerating the process of vascular remodeling and healing.

## Project Status

The MINT team has successfully completed in vitro studies of Zone, demonstrating the ability of the device to isolate a segment of a simulated vessel, maintain tight seals around the isolated region, and permit distal flow through the bypass channel.

Currently designed to treat abdominal aortic aneurysms and trauma to the aorta, Zone will be scaled and tested for treatment of vascular diseases and trauma to the peripheral vascular system, including injuries to the femoral and iliac arteries and veins.

## Intellectual Property

MINT has filed 10 patent applications for Zone and Injectable Mold in the United States and internationally.